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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/587,789	03/03/2008	Ezri Peleg	27275.005	6930
27887 FENNEMORE	7590 03/01/201 CRAIG	1	EXAMINER	
3003 NORTH (	CENTRAL AVENUE		BUI, PHUONG T	
SUITE 2600 PHOENIX, AZ 85012			ART UNIT	PAPER NUMBER
			1638	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)
	10/587,789	PELEG ET AL.
Office Action Summary	Examiner	Art Unit
	Phuong T. Bui	1638
The MAILING DATE of this communication app Period for Reply	ears on the cover sheet with the c	correspondence address
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA  - Extensions of time may be available under the provisions of 37 CFR 1.1: after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period v  - Failure to reply within the set or extended period for reply will, by statute. Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tin will apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE	N. nely filed the mailing date of this communication. D (35 U.S.C. § 133).
Status		
1) ☐ Responsive to communication(s) filed on <u>9/20/</u> 2a) ☐ This action is <b>FINAL</b> . 2b) ☐ This 3) ☐ Since this application is in condition for allowar closed in accordance with the practice under E	action is non-final. nce except for formal matters, pro	
Disposition of Claims		
4) ☐ Claim(s) 1-38 is/are pending in the application. 4a) Of the above claim(s) is/are withdray 5) ☐ Claim(s) is/are allowed. 6) ☐ Claim(s) 1-38 is/are rejected. 7) ☐ Claim(s) is/are objected to. 8) ☐ Claim(s) are subject to restriction and/o	vn from consideration.	
Application Papers		
9) The specification is objected to by the Examine 10) The drawing(s) filed on is/are: a) accomplicant may not request that any objection to the Replacement drawing sheet(s) including the correct 11) The oath or declaration is objected to by the Examine	epted or b) objected to by the Idrawing(s) be held in abeyance. See ion is required if the drawing(s) is obj	e 37 CFR 1.85(a). jected to. See 37 CFR 1.121(d).
Priority under 35 U.S.C. § 119		
12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of:  1. Certified copies of the priority documents 2. Certified copies of the priority documents 3. Copies of the certified copies of the priority documents application from the International Bureau * See the attached detailed Office action for a list	s have been received. s have been received in Applicati rity documents have been receive I (PCT Rule 17.2(a)).	on No ed in this National Stage
Attachment(s)  1) Notice of References Cited (PTO-892)  2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  3) Information Disclosure Statement(s) (PTO/SB/08)  Paper No(s)/Mail Date 1/8/07.	4)  Interview Summary Paper No(s)/Mail Da 5)  Notice of Informal P 6)  Other: <u>37CFR1.105</u>	ate Patent Application

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#### **DETAILED ACTION**

1. The Office acknowledges the receipt of Applicant's restriction election filed September 20, 2010 and Supplemental Response filed October 5, 2010. Applicant elects Group IV, tomato variety HA3518 with traverse, stating primarily that the dg mutant plants of Levin also contain undesirable traits linked to the dq mutation and were not screened to be devoid of undesirable traits. The Declaration of Peleg states LRT915 of Levin is pleiotropic in traits and lower than 200 ppm in lycopene content. The Declaration and Applicant's traversals have been carefully considered but are deemed unpersuasive because "deleterious traits" is a subjective term not clearly defined in the specification. Page 4 gives examples of deleterious traits but does not provide a definition to allow one skilled in the art to objectively determine deleterious traits. Moreover, since HA3518 is a hybrid, its F1 and F2 progenies claimed are not required to retain any of the traits of HA3518 or the homozygous dq mutation. Traversals with regard to the screening steps are not commensurate in scope with the claims because the product claims do not require a screening step. The Declaration does not address the broad scope of the claims. This restriction is maintained and made FINAL. Claims 1-38 are pending and are examined to the extent of tomato variety HA3518. Varieties HA3512, HA3513 and HA3519 are withdrawn from examination. Applicant earliest priority benefit is January 29, 2004.

Nonelected inventions should be deleted from the claims.

#### Information Disclosure Statement

2. Applicant's IDS filed January 8, 2007 has been considered. A signed copy is

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attached.

# Specification

3. The disclosure is objected to because of the following informalities:

Page 16 refers to Table 1 but there is only Tables 2 and 3.

The specification must be updated to include the Accession No. See pages 4 and 12, for example.

Appropriate correction is required.

## Claim Objections

4. Claims 35 and 36 are objected to because of the following informalities:

Claim 35 is an improper multiple dependent claim.

Appropriate correction is required.

### Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, "robust" and "deleterious traits" are relative terms lacking a comparative basis. It is unclear what values are encompassed by "average content in currently available varieties", as what is available varies from season to season and year to year. All subsequent recitations of "robust", "deleterious traits" and "average content in currently available varieties" are also rejected.

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In claim 3, it is unclear whether the claimed hybrid is homozygous for the *dg* mutation and has all the traits set forth in claim 1. See also claim 10.

In claim 5, "poor", "shallow", "brittle", "thin", "fragile", "premature", "low" and "small" are relative terms lacking a comparative basis. All subsequent recitations of these terms are also rejected.

In claim 18, "improved nutritional value" is a relative term lacking a comparative basis. Also, it is not a trait. It is suggested this recitation be deleted.

In claim 22, "parts" should be amended to "part" for proper antecedence. See also claim 23.

In claim 24, the second recitation of "a" should be amended to "the" for proper antecedence.

In claim 25, "A" should be amended to "The" for proper antecedence.

In claim 28, "a variety" should be amended to "the variety" for proper antecedence.

In claim 32, it is unclear which plant "according to the present invention" is being used in step (a), as the application discloses several hybrid plants. Also, it is unclear whether "a hybrid tomato variety" in the preamble is the same as "a first plant that is a hybrid plant" in step (a).

Claim 33 is an incomplete method claim because when "a hybrid tomato variety" in the preamble of claim 32 is replaced with HA3518, none of the steps set forth in claim 32 requires HA3518.

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In claim 35, "a non-transformed tomato plant according to claim 1" lacks antecedence.

In claim 37, "A" should be amended to "The" for proper antecedence.

In claim 37, it is unclear how "single trait conversion" is defined--does Applicant mean single locus or gene conversion?

In claim 38, "improved nutritional value" is a relative term lacking a comparative basis. Also, "improved nutritional value" is not a single trait conversion. It is suggested this recitation be deleted.

Clarification and/or correction is required.

# Claim Rejections - 35 USC § 112, 1st paragraph

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 6, 7, 13, 14, 26, 27, 33 and 34 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Since the seed claimed is essential to the claimed invention, it must be obtainable by a reproducible method set forth in the specification or otherwise be readily available to the public. If a seed is not so obtainable or available, a deposit thereof may satisfy the requirements of 35 U.S.C. 112. The specification does not disclose a reproducible process to obtain the exact same seed in each occurrence and it is not

apparent if such a seed is readily available to the public. If the deposit of the seed is made under the terms of the Budapest Treaty, then an affidavit or declaration by the Applicant, or a statement by an attorney of record over his or her signature and registration number, stating the seed have been deposited under the Budapest Treaty and that the seed will be irrevocably, and without restriction or condition, released to the public upon the issuance of a patent would satisfy the deposit requirement made herein. A minimum deposit of 2500 seeds is considered sufficient in the ordinary case to assure availability through the period for which a deposit must be maintained.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809, Applicant may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number showing that

- (a) during the pendency of the application, access to the invention will be afforded to the Commissioner upon request;
- (b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;
- (c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the enforceable life of the patent, whichever is longer;
- (d) the viability of the biological material at the time of deposit will be tested (see 37 CFR 1.807); and
  - (e) the deposit will be replaced if it should ever become unviable.

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Claims 6, 13 and 33 do not recite deposit information. Applicant does not teach a reproducible method of producing HA3518 or that HA3518 is publicly available. One skilled in the art cannot make and use HA3518 absent a deposit without undue experimentation. Furthermore, Applicant does not indicate Applicant will comply with all requirements set forth under 37 CFR 1.801-1.809.

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9. Claims 1-5, 8-12, 15-25, 28-32 and 35-38 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for deposited variety HA3518, does not reasonably provide enablement for any tomato plant which is homozygous for *dg* with a 2-fold increase in lycopene content and devoid of deleterious traits, methods of using said plant and progenies obtained therefrom. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The breadth of the claims encompasses any tomato plant which is homozygous for the dg mutation, a two-fold higher level of lycopene content and devoid of deleterious traits associated with the dg mutation. The specification states that pleiotropic, undesired agronomic traits are linked to the dg mutation (p. 3, 8). Applicant states the prior art was unable to separate "pleiotropic, undesired traits linked to the dg mutation (p. 3). Applicant does not teach how to separate the desirable traits from the undesirable traits associated with the dg mutation. Applicant does not disclose how to obtain the claimed plant. Applicant does not teach which plants should be used in the cross to obtain the plant having the claimed characteristics. Steps (1)-(5) on pages 10-

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11 of the specification teach how to select for plants homozygous for the *dg* mutation, but does not teach which plants are used in the crosses, how to determine plants having "minimal pleiotropic effects", what "superior commercial varieties" were used in the crosses and how often steps (1) to (5) were repeated to obtain "best performing plants". While one skilled in the art can readily cross two different tomato plants, further guidance is necessary as to what tomato plants are to be crossed to obtain the characteristics set forth in the claims and devoid of the deleterious traits which are linked to the *dg* mutation. Since the plant homozygous for the dg mutation is not enabled, methods using said plant and progenies obtained therefrom are also not enabled. Accordingly, Applicant has not enabled the claimed invention as commensurate in scope with the claims without undue experimentation.

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10. Claims 1-5, 8-12, 15-25, 29-32 and 35-38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

HA3518 is a hybrid (p. 16) and thus is not homozygous at every allele. HA3518 is not representative of the genus of tomato varieties claimed. There is inadequate written description provided for other alleles of the tomato varieties claimed. While the hybrid HA3518 has the homozygous *dg* mutation, two-fold lycopene content and "devoid of deleterious traits" which are undefined, one skilled in the art cannot reliably predict the genetic makeup or morphological and physiological characteristics of other

tomato varieties based upon the disclosure of HA3518. The dg gene is not representative of other tomato genes. Thus, Applicant is not in possession of the genus of tomato varieties claimed. Claims 15-27, 29, 30, 37 and 38 are drawn to F1 progenies of hybrid HA3518. Claims 31 and 36 are drawn to F2 progenies of hybrid HA3518. While F1 progenies of an inbred plant would have the same allele at every locus as the inbred parent, F1 progenies of hybrid HA3518 would not, because it is unpredictable which allele of the parent hybrid would be inherited. The claims do not require progenies of HA3518 to retain all the morphological and physiological characteristics of the hybrid parent HA3518. Applicant has not adequately described F1 or F2 progenies of hybrid HA3518. The claims are drawn to progeny plants having undisclosed identifying characteristics whereby only one parent in the first cross is partially identified. and none of the parents in the subsequent cross is known. No information is given with regard to the second parent in the first or subsequent crosses. If the claimed F1 plant cannot be identified by any of the characteristics of the HA3518 parent, then it is not possible to determine what characteristics F2 progeny would possess. There are insufficient relevant identifying characteristics to allow one skilled in the art to predictably determine the genomic structure or phenotypic characteristics of the claimed progenies, absent further guidance. Methods of using the plant also lack written description because the starting material is not adequate described, and the steps do not recite what traits or characteristics are being selected for in the progeny plants.

Claim 37 recites at least one single trait conversion anywhere in the plant genome and conferring any trait(s). The specification does not describe any single trait

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conversion encompassed by the claims. The specification does not describe the structure(s) of any such single trait conversion. The breadth of the claim encompasses a plant whereby every trait has been converted. There are insufficient relevant identifying characteristics to allow one skilled in the art to predictably determine such single trait conversion. Given the breadth of the claims and lack of guidance of the specification, the specification fails to provide an adequate written description of the plant encompassed by the claim.

Accordingly, the claimed invention lacks adequate written description under current written description guidelines.

### Claim Rejections - 35 USC § 102 and 103

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
- 12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

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Claims 1-5, 8-12, 15-17, 24, 25, 28-32, 36 and 37 are rejected under 35 13. U.S.C. 102(e) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Levin et al. (WO 03/057917, published July 17, 2003 (Applicant's IDS)). Levin teaches a tomato variety homozygous for the dg mutation with "significantly elevated levels of ...lycopene", whereby the da mutation was "introgressed into several commercial processing and fresh-market tomato cultivars that are currently marketed as Lycopene Rich Tomatoes (LRT)" (p. 2). Levin states "Red-ripe fruit of the dg mutants are significantly more crack resistant and therefore of higher quality" (p. 3). The plant of Levin appears to be a stable parent line and hybrid, devoid of "deleterious traits" which are undefined, and "at least 200 ppm plus or minus the standard error from the mean" (Tables 1 and 4). Levin also teaches seed (p. 6), F1 and F2 generation plants (pp. 7-8, Examples), methods for using the dq-mutated plant in crosses (pp. 7-8), pollen, ovule and tissue culture which are inherent in the claimed plants. It should be noted that F2 generation plants and plants comprising a single trait conversion read on any tomato plant, because the claimed plants are not required to retain the dg allele or any of the morphological and physiological characteristics of the parent hybrid. There are insufficient identifying characteristics set forth in the claims to distinguish the claimed plants from those of the prior art. Only one parent in the first cross is partially characterized. The second parent in the first cross and both parents in the second cross are unknown. The claims do not specifically recite a plant whereby the plants are homozygous for the dq mutation and retain all of the physiological and morphological characteristics of the deposited line. Accordingly, the claimed invention is anticipated

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by, or in the alternative, is obvious in view of the prior art. See *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985), which teaches that a product-by-process claim may be properly rejected over prior art teaching the same product produced by a different process, if the process of making the product fails to distinguish the two products. Since the Patent Office does not have the facilities to examine and compare the plant of Applicant's with that of the prior art, the burden of proof is upon the Applicant to show an unobvious distinction between the claimed plant and the plant of the prior art. See *In re Best*, 562F.2d 1252, 195 USPQ 430 (CCPA 1977).

14. Claims 31 and 36-38 are rejected under 35 U.S.C. 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over (Hoogstraten, J. (USPN 6414226 (A)). The claims are drawn to the F2 generation progeny plants and plants comprising a single trait conversion. The claimed plants are not required to retain the *dg* allele or any of the morphological and physiological characteristics of the parent hybrid HA3518. The prior art teaches a tomato plant, seed and a tomato plant containing a single trait conversion conferring male sterility (see claim 29). There are insufficient identifying characteristics set forth in the claims to distinguish the claimed plants from those of the prior art. Both parents in the second cross are unknown. The claims do not specifically recite a plant whereby the plants are homozygous for the *dg* mutation and retain all of the physiological and morphological characteristics of the deposited line. Accordingly, the claimed invention is anticipated by, or in the alternative, is obvious in view of the prior art. See *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985), which teaches that a product-by-process claim may be properly rejected over

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prior art teaching the same product produced by a different process, if the process of making the product fails to distinguish the two products. Since the Patent Office does not have the facilities to examine and compare the plant of Applicant's with that of the prior art, the burden of proof is upon the Applicant to show an unobvious distinction between the claimed plant and the plant of the prior art. See *In re Best*, 562F.2d 1252, 195 USPQ 430 (CCPA 1977).

15. Claims 1-5, 8-12, 15-25, 28-32 and 36-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levin et al. (WO 03/057917, published July 17, 2003 (Applicant's IDS)), as applied to claims 1-5, 8-12, 15-17, 24, 25, 28-32, 36 and 37 above and further in view of Hoogstraten, J. (USPN 6414226 (A)).

The teachings of Levin have been discussed supra.

Levin does not teach inclusion of an additional trait or gene.

Hoogstraten teaches introduction and expression of a transgene to confer additional traits into a tomato plant by genetic transformation or crossing, whereby the traits include herbicide resistance and disease resistance, and the transgene is operably linked to a regulatory element such as a promoter (claim 24). Hoogstraten also teaches a single trait conversion (claim 29).

It would have been *prima facie* obvious to one skilled in the art at the time the invention was made to introduce additional genes into the plant of Levin for the purpose of conferring additional desirable traits or properties such as herbicide and disease resistance by known methods such as crossing, transformation or single trait conversion

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as taught by Hoogstraten. One skilled in the art would have been motivated to do so with a reasonable expectation of success.

#### Conclusion

- 16. No claim is allowed.
- 17. Any inquiry concerning this communications from the Examiner should be directed to Phuong Bui, whose telephone number 571-272-0793.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Anne Marie Grunberg, can be reached at 571-272-0975.

The fax phone number for the organization where this application or proceeding is assigned, for sending official correspondence, is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet.

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Phuong T. Bui/ Primary Examiner, Art Unit 1638

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### ATTACHMENT TO OFFICE ACTION

# Request for Information under 37 CFR § 1.105

1. Applicant and the assignee of this application are required under 37 CFR § 1.105 to provide the following information that the examiner has determined is reasonably necessary to the examination of this application.

2. This request is being made for the following reasons:

Applicant is claiming variety HA3518, but the instant specification is silent about what starting materials and methods were used to produce plant variety HA3518. The information provided on page 10 is insufficient. The requested information is required to make a meaningful and complete search of the prior art.

- 3. In response to this requirement, if known, please provide answers to each of the following interrogatories eliciting factual information:
  - (i) Please supply the breeding methodology and history regarding the development of the instant variety.
  - a) Such information should include all of the public or commercial designations/denominations used for the original parental lines.
  - b) Information pertaining to the public availability of the original parental lines should be set forth.
  - c) The breeding method used should be set forth, such as whether single seed descent, bulk method, backcross method, or some other method was used.
    - d) The filial generation in which the instant plant was chosen should be set forth.

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e) Information pertaining to the homozygosity or heterozygosity of the parents as well as the instant plant should be set forth.

- f) Are there any patent applications or patents in which sibs or parents of the instant plant are claimed? If so, please set forth serial numbers and names of the sibs or parents.
- 4. If Applicant views any or all of the above requested information as a <u>Trade</u>

  <u>Secret</u>, then Applicant should follow the guidance of MPEP § 724.02 when submitting the requested information.
- 5. In responding to those requirements that require copies of documents, where the document is a bound text or a single article over 50 pages, the requirement may be met by providing copies of those pages that provide the particular subject matter indicated in the requirement, or where such subject matter is not indicated, the subject matter found in applicant's disclosure. Please indicate where the relevant information can be found.
- 6. The fee and certification requirements of 37 CFR § 1.97 are waived for those documents submitted in reply to this requirement. This waiver extends only to those documents within the scope of this requirement under 37 CFR § 1.105 that are included in the applicant's first complete communication responding to this requirement. Any supplemental replies subsequent to the first communication responding to this requirement and any information disclosures beyond the scope of this requirement under 37 CFR § 1.105 are subject to the fee and certification requirements of 37 CFR § 1.97 if submitted subsequent to a first Office action on the merits.

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7. The applicant is reminded that the reply to this requirement must be made with

candor and good faith under 37 CFR § 1.56. Where the applicant does not have or

cannot readily obtain an item of required information, a statement that the item is

unknown or cannot be readily obtained may be accepted as a complete reply to the

requirement for that item.

8. Any inquiry concerning this communication or earlier communications from the

examiner should be directed to Phuong Bui whose telephone number is 571-272-0793.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone

number for the organization where this application or proceeding is assigned is 571-

273-8300.

/Anne Marie Grunberg/

Supervisory Patent Examiner, Art Unit 1638